



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 2, 2017

Jessica Fernandez
Registration Manager
Bayer CropScience, LP
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: PRIA Label Amendment – Additional New Uses: basil (dried and fresh leaves);
brassica, vegetable, head and stem, group 5-16; celtuce, cilantro (fresh leaves);
cotton, subgroup 20C; fennel and florence both fresh leaves and stalk; kohlrabi;
leafy vegetable subgroup 4-16; and leaf petiole vegetable, subgroup 22B
Product Name: Fenamidone Technical
EPA Registration Number: 264-693
Application Date: 12/22/2015
Decision Number: 512550

Dear Ms. Fernandez:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(B), subject to the following conditions:

1. You must submit and/or cite all data required for registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. You are required to comply with the data requirements described in the DCI identified below. It can be viewed at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0048-0019>
 - a. Fenamidone GDCI-046679-1446

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR

152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Marcel Howard by phone at (703)305-6784, or via email at howard.marcel@epa.gov.

Sincerely,



Cynthia Giles-Parker, Chief
Fungicide Branch
Registration Division (7505P)

Enclosure- stamped "accepted" label

FENAMIDONE Technical

For Formulation of Fungicides Only.

Formulators who use this product are responsible for obtaining EPA registration for their formulated products.

ACTIVE INGREDIENT:

Fenamidone: (5S)-3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-4H-imidazol-4-one..... **98.5%**

OTHER INGREDIENTS: **1.5%**

TOTAL: **100.0%**

EPA Reg. No. 264-693

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

Please refer to [back panel] [booklet] for additional precautionary statements and directions for use. [Note to reviewer: Location of additional precautionary statements and directions for use will vary between those listed, depending on container type/size.]

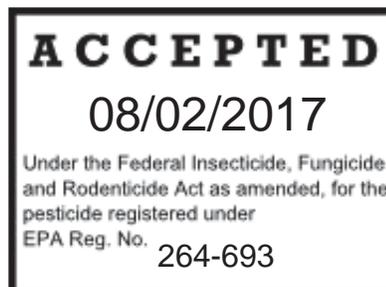
FIRST AID

| | |
|--------------------------------|---|
| IF ON SKIN OR CLOTHING: | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |
| IF SWALLOWED: | <ul style="list-style-type: none">• Immediately call a poison control center or doctor for treatment advice.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Have person sip a glass of water if able to swallow.• Do not give anything by mouth to an unconscious person. |
| IF IN EYES: | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice. |

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Possible mucosal damage may contraindicate the use of gastric lavage. May pose an aspiration pneumonia hazard.



PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its label.

For use only by manufacturers in the formulation of fungicides. This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements regarding the support of such use(s).

Only For Formulation Into a Fungicide for use on crops: root vegetable subgroup 1B (except radish and sugar beet); potatoes (including potato seed pieces) and other tuberous and corm vegetable subgroup 1C; cottonseed subgroup 20C; cucurbit vegetables group 9; brassica head and stem vegetable group 5-16; leafy vegetables group 4-16; basil; bulb onion subgroup 3-07A; green onion subgroup 3-07B; leaf petiole vegetables subgroup 22B; celtuce; fennel, Florence; kohlrabi; tomatoes; peppers and other fruiting vegetable group 8; tobacco; grapes (Only east of Rocky Mountains); ginseng; succulent bean (except cowpea); sunflower (seed treatment); and greenhouse ornamentals. This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s). This product is not registered for use at residential sites.

STORAGE AND DISPOSAL

PESTICIDE STORAGE

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING

[Dilutable Manufacturing Use Products in Non-Refillable Plastic Containers]

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs) Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into manufacturing equipment. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into manufacturing equipment. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into manufacturing equipment. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into manufacturing equipment. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Dilutable Manufacturing Use Products in Non-Refillable Metal Containers]

Nonrefillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Any dilutable pesticides in containers too large to shake (larger than 5 gallons or 50 pounds)

Triple Rinse as follows: Empty remaining contents into manufacturing equipment. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into manufacturing equipment or store rinsate for later use or disposal. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Non-Dilutable Manufacturing Use Products in Non-Refillable Containers]

Manufacturing Use Products in Non-Refillable Fiber Drums with Liners

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into manufacturing equipment, then offer for recycling if available or dispose of in a sanitary landfill or by incineration. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

Manufacturing Use Products in Non-rigid, Non-Refillable Containers

Nonrefillable container. Do not reuse or refill this container. Completely empty container into manufacturing equipment. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

[Manufacturing Use Products in Refillable Containers]

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781) or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into manufacturing equipment. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into manufacturing equipment while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, and Kegs)

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into manufacturing equipment. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into manufacturing equipment. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container.

DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

THE MANUFACTURER EXPRESSLY DISCLAIMS ALL LIABILITY FOR CLAIMS AND ACTIONS (WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR BREACH OF WARRANTY) ARISING OUT OF, RESULTING FROM OR CONNECTED WITH A FORMULATION CONTAINING THIS PRODUCT WHEN USED FOR ANY PURPOSE OTHER THAN THOSE USES SET FORTH ABOVE. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE ABOVE.

ANY FORMULATOR OR BUYER WHO USES THIS PRODUCT IN FORMULATIONS FOR ANY USE OTHER THAN THOSE STATED ABOVE ASSUMES ALL LIABILITY FOR CLAIMS AND ACTIONS ARISING OUT OF, CONNECTED WITH OR RESULTING FROM SUCH USE AND AGREES BY SO USING THIS PRODUCT TO INDEMNIFY AND HOLD HARMLESS THE MANUFACTURER FROM SUCH CLAIMS AND ACTIONS.

THIS DISCLAIMER AND INDEMNITY IS IN ADDITION TO, NOT IN LIEU OF, THE BELOW DISCLAIMER AND LIMITATIONS.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

PRODUCED FOR



Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

Fenamidone Technical (PENDING) 08/04/2015, 12/15/2015, 03/20/2017, 06/07/2017, 06/30/2017